

(2) *Limitations*. As in paragraph (d)(5)(ii)(A)(2) of this section.

(iii) *Swine*—(A) *Amount*. 10 mg/lb body weight daily, for 3 to 5 days.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae*, and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations*. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to swine within 24 hours of slaughter.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 mg/lb body weight daily in divided doses, for 3 to 5 days.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Histophilus* spp., and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations*. Prepare fresh solution daily; use as a drench; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to cattle within 24 hours of slaughter; do not use in lactating dairy cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 61015, Nov. 19, 1993; 59 FR 39439, Aug. 3, 1994; 60 FR 26827, May 19, 1995; 60 FR 47052, Sept. 11, 1995; 62 FR 27691, May 21, 1997; 62 FR 35076, June 30, 1997; 62 FR 60656, Nov. 12, 1997; 64 FR 37673, July 13, 1999; 65 FR 10706, Feb. 29, 2000; 66 FR 35898, July 10, 2001; 67 FR 78355, Dec. 24, 2002; 69 FR 62406, Oct. 26, 2004; 72 FR 1174, Jan. 10, 2007; 72 FR 63987, Nov. 14, 2007; 73 FR 35340, June 23, 2008; 74 FR 62491, Nov. 30, 2009. Redesignated and amended at 76 FR 49649, Aug. 11, 2011; 77 FR 5700, Feb. 6, 2012]

#### § 520.443 Chlortetracycline tablets and boluses.

(a) *Specifications*. Each tablet/bolus contains 25, 250, or 500 milligrams (mg) chlortetracycline hydrochloride.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.150 of this chapter.

(d) *Conditions of use in calves*—(1) *Amount*. One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(ii) *Limitations*. Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount*. One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount*. One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more

## § 520.445

than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002. Redesignated and amended at 76 FR 49649, Aug. 11, 2011]

### § 520.445 Chlortetracycline and sulfamethazine powder.

(a) *Specifications.* Each pound of soluble powder contains chlortetracycline bisulfate equivalent to 102.4 grams (g) of chlortetracycline hydrochloride and sulfamethazine bisulfate equivalent to 102.4 g of sulfamethazine.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use in swine.* Administer in drinking water as follows:

(1) *Amount.* 250 milligrams (mg) of chlortetracycline and 250 mg of sulfamethazine per gallon.

(2) *Indications for use.* For the prevention and treatment of bacterial enteritis; as an aid in the reduction of the incidence of cervical abscesses; and as an aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations.* Use as the sole source of chlortetracycline and sulfonamide. Not to be used for more than 28 consecutive days. Withdraw 15 days before slaughter.

[76 FR 49649, Aug. 11, 2011]

### § 520.446 Clindamycin capsules and tablets.

(a) *Specifications*—(1) Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.

(2) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(3) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000009 and 059130 for use of capsules described in paragraph (a)(1) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.

## 21 CFR Ch. I (4–1–12 Edition)

(3) No. 043806 for use of tablets described in paragraph (a)(3) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F. necrophorum*, and *C. perfringens*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 54954, Aug. 27, 2002, as amended at 68 FR 55824, Sept. 29, 2003; 69 FR 32273, June 9, 2004; 71 FR 39204, July 12, 2006; 73 FR 4077, Jan. 24, 2008]

### § 520.447 Clindamycin solution.

(a) *Specifications.* Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors.* See Nos. 000009, 051311, 058829, and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses